Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter.

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards.In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may be not totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is medical device, which can be used repeatedly.

WARNING:

- **Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.**
- **Testee can not use enamel or other makeup.**
- **Testee's fingernail can not be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

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1 Safety

1.1 Instructions for safe operations

✧ Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the device.

✧ Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.

✧ The oximeter cannot be used together with devices not specified in User's Manual. Only the accessory that is appointed or recommendatory by manufacture can be used with this device.

✧ This product is calibrated before leaving factory.

1.2 Warning

Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.

DO NOT use the oximeter while the testee measured by MRI and CT.

The person who is allergic to rubber can not use this device.

The disposal of scrap instrument and its accessories and packing (including plastic bags, foams and paper boxes) should follow the local laws and regulations.

Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

Please choose the accessories which are approved or manufactured by the manufacturer, or else it may damage the device.

Please don't measure this device with functional tester for the device's related information.

1.3 Attention

Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.

If the oximeter gets wet, please stop operating it.

When it is carried from cold environment to warm or humid environment, please do not use it immediately.

High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1) for instructions of cleaning and disinfection.

Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.

When cleaning the device with water, the temperature should be lower than 60℃.

The pulse oximeter is suitable used for adult.

As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thicker finger such as thumb and middle finger deeply enough into the probe.

The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.

The device should be used with computer by affiliated software.

🔔 Please read the measured value when the waveform on screen is equably and steady-going。The measured value is optimal value,and the waveform at the moment is the standard one.

🔔 If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.

🔔 The device has the function of limits alarming,.When the alarm happens,the screen will appear prompt information.

🔔 The device has normal useful life for three years since the first electrified use.

🔔 The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.

🔔 Do not contort or drag the wire of the device.

2 Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

The Pulse Oximeter features in small volume, low-power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a probe for diagnosis, and a display interface will directly show the measured value of pulse oxygen saturation with the high veracity and repetition.

2.1 Features

A. Operation of the product is simple and convenient.

B. The product is small in volume, light in weight and convenient in carrying.

C. Low-power consumption.

2.2 Major applications and scope of application

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger. The product is suitable for being used in family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports and it is not recommended to use the device during the process of having sport) and so on.

⚠**The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3 Environment requirements

Storage Environment

a) Temperature :-40℃～+60℃

b) Relative Humidity :5%～95%

c) Atmospheric pressure :500hPa～1060hPa

Operating Environment

a) Temperature:10℃～40℃

b) Relative Humidity :30%～75%

c) Atmospheric pressure:700hPa～1060hPa

3 Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on display of computer through treatment in electronic circuits and microprocessor.

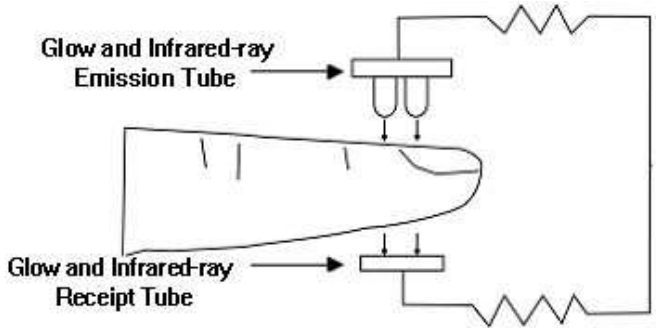

Figure 1

4 Technical specifications

4.1 Main performance

A. Used with affiliated software.

B. SpO_2 value display

C. Pulse rate value display, bar graph display

D. Pulse waveform display

E. With alarm function

F. With data review function

4.2 Main Parameters

A. Measurement of SpO_2

Measuring range: 0%～100％

Accuracy: When the SpO_2 measuring range is 70%～100％,the permission of absolute error is ±2％;

below 70% unspecified

B. Measurement of pulse rate

Measuring range:30bpm～250bpm

Accuracy: ±2 bpm or ±2% (select larger)

C. Resolution

SpO_2 : 1%, Pulse rate: 1bpm.

D. Measurement Performance in Weak Filling Condition

SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).

E. Resistance to surrounding light

The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

F. Power supply requirement: 5V DC

G. Optical Sensor

Red light (wavelength is 660nm，6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range

SpO_2 **:** 0%~100%

Pulse Rate: 30bpm~250bpm

5 Installation

5.1 View of the device

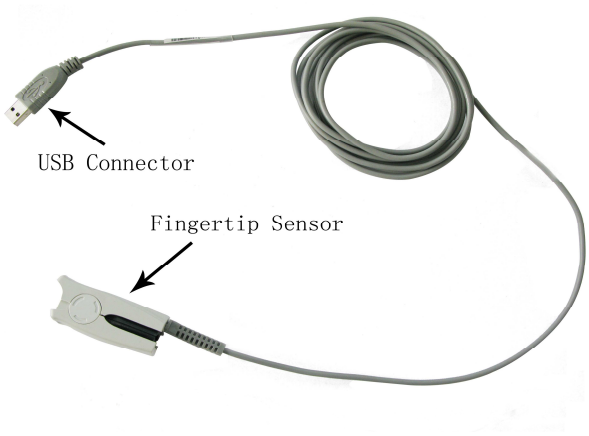

Figure 2.sketch map of the device

5.2 Accessories

A. A User Manual

B. A disk (PC software and the user manual of software)

6 Operating Guide

6.1 Application method

6.1.1 Installation and startup of software

A First, please install the affiliated software into the computer, two icons would appear on the desktop after installation. The icon of SpO2 is the program for receiving real-time data which is shown as figure 3; the icon of SpO2 Review is the program for receiving stored data which is shown

as figure 4.

Figure 3.SpO2 program

Figure 4 SpO2 Review program

B Double click the red icon to start real-time measure program.If you are using the software for the first time ,there will appear a dialog box ,you could choose the language as you like.

6.1.2 Collect Data

The program could identify the inserted device automatically.Connect the device to the computer,then place your finger right in the device,the real-time measure for SpO2 and pulse will begin.

⚠ **Fingernails and the luminescent tube should be on the same side,and try your best to make the position corresponding.**

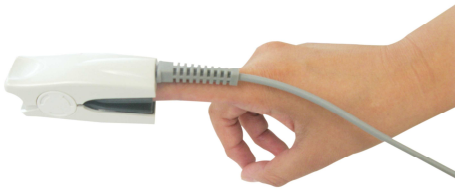

Figure 5.finger position sketch map

6.1.3 Save data

A When real-time measuring, 'New Session' will appear if you click the waveform area with right key;click 'New Session' ,there will be a dialog box to clew you to close the dialog or not.If you choose yes,there will be a saving-data dialog box,or else measure will be continued.

B When you close SpO2 program after accomplishing real-time measure ,there will be also a saving-data dialog box to clew you to save the measure data.

If you have filled individual information in the dialog box of patient message before,this dialog box will display the content that you have filled in;if you have not ,you could fill information in the dialog box ,click 'ok' to save data.

After saving data accurately,you have accomplished the whole measurement.If you want to

review saved data,please use 'SpO2 Review ' program.

⚠**Please refer to user manual of the software for the particular introduction。**

6.2 Attention for operation

A. Please check the device before using, and confirm that it can work normally.

B.The finger should be placed in proper position (see the attached illustration of figure 5 for reference), or else it may result in inaccurate measurement.

C.There should be subject's arteriole between the luminous and photosensitive sensors when measuring.

D. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.

E. Do not fix the SpO_2 sensor with barrier such as adhesive, or else it may result in inaccurate measure of SpO_2 and pulse rate.

F. Excessive ambient light may affect the measurement result.,such as fluorescent lamp, dual ruby light, infrared heater and direct sunlight.

G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

H. Testee can not use enamel or other makeup.

I. Please clean and disinfect the device according to the User Manual (7.1) after operating.

6.3 Clinical restrictions

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. For those with a substantial amount of staining dilution drug (such as ethylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.

C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor resulted in serious error of SpO_2 measure.

D. As the SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

7 Maintain、transportation and storage

7.1 Cleaning and Disinfecting

Using medical alcohol to disinfect the device, nature dry or clean it with clean soft cloth.

7.2 Maintain

A. Please clean and disinfect the device before using according to the User Manual(7.1).

B. The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3 Transportation and storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive material.

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C~60°C; Humidity: ≤95%

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally.	1. The finger position is not proper. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try a few times again and go to hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably.	1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep still.
It cannot display the interface of the software.	1.The USB plug doesn't connected well. 2.The software can't identify. 3.The device is damaged.	1.Connect the USB plug with computer again. 2.Close the software and open it again. 3.Please contact the local service center.

9 Key of Symbols

Signal	Description
	Warning – See User Manual
	The pulse oxygen saturation (%)
bpm	Pulse rate (bpm)
SN	Serial number
	USB

10 Function Specification

SpO_2 Parameter Specification	
Measuring range	0%～100% (the resolution is 1%).
Accuracy	70%～100%：±2%, Below 70% unspecified.
Average value	Calculate the Average value in every 4 measure value. The deviation between average value and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30bpm～250bpm, (the resolution is 1bpm)
Accuracy	±2bpm or±2% (select larger)
Average pulse rate	Moving calculate the Average pulse rate every 4 cardio-beat's cycle. The deviation between average value and true value does not exceed 1%
Safety Type	BF Type
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate, the stronger pulse.
Power Supply Requirement	
5V DC USB power supply	
Oximeter Probe	
Wavelength:660nm 880nm	
Dimensions and Weight	
Dimensions	About 1.5m for the length of wire.
Weight	About 40 g